GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2448
ANSWERED ON:15.12.2004
REGISTRATION SYSTEM FOR IMPORTED DRUGS
Paraste Shri Dalpat Singh

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Registration system for the imported drugs was started to prevent the inflow of substandard medicines into the country;

(b) if so, the details regarding the companies which came forward for Registration during the last three years and registered without even inspecting the premises as per the Drugs and Cosmetic Act ;

(c) if so, whether the Government in such cases ensure that these companies are following the WHO GMP ; and

(d) if so, the details thereof ?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) Yes, Sir. Under the New system of registration of import of drugs in the country, which came in to force on Ist April 2003 vide Ministry of Health Notification No. GSR 604 (E) dated 24.8.2001; no drug can be imported in the country without manufacturing site registration and import licence in Form 10 of the Drugs & Cosmetics Rules.

(b) to (d) The details regarding applications received for manufacturing site registration alongwith their drugs and manufacturing site registered upto 31st October, 2004 are available in the department`s website www.cdsco.nic.in which is being updated from time to time.

Inspection of overseas manufacturing sites is not a mandatory criteria for registration of import of drugs. Presently, such imported drugs, which have been in use in the country for considerable period and are duly approved, have been registered, provided all formalities prescribed in Schedule D (I) & D (II) of the Drugs & Cosmetics Rules are complied with. The applicants are also required to submit regulatory status of the drug, free sale certificate and GMP certificate in WHO format or certificate of pharmaceutical product (CPP), issued by regulatory authority of the country of origin and free sale approval issued by the regulatory authorities of other major countries.